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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------|---------------------|------------------|
| 09/555,987 | 09/11/2000 | John P. Vanden Heuvel | 7024465PUR99 | 9345 |
| 7590 | 09/22/2004 | | EXAMINER | |
| Henry D Coleman COLEMAN SUDOL SAPONE P C 714 Colorado Avenue Bridgeport, CT 06605-1601 | | | HUI, SAN MING R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/555,987 | VANDEN HEUVEL ET AL. | |
| | Examiner San-ming Hui | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 June 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Applicant's amendments filed JUNE 9, 2004 have been entered.

The addition of claims 23-24 is acknowledged. Claims 1-24 are pending.

The outstanding rejections under 35 USC 103(a) are withdrawn in view of the amendments filed JUNE 9, 2004.

New ground of rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boer et al. (US Patent 5,518,751) in view of Cook et al. (US Patent 5,554,646 from the IDS received September 6, 2000) and Francisco et al., ("Diabetes Mellitus" in *Pharmacotherapy: A Pathophysiologic Approach*, 2nd ed., 1992, pages 1121-1127).

de Boer et al. teaches that unsaturated fatty acid, preferably CLA, in food compositions such as milk products are useful in treating disorders such as diabetes (See particularly col. 1, line 35 to 43).

de Boer et al. does not expressly teach particularly CLA is useful in a method of treating diabetic symptoms of elevated insulin and glucose intolerance. de Boer et al. does not expressly teach that the conjugated linoleic acid is *trans,cis*-9,11-octadecainoic acid, *cis,cis*-9,11-octadecadienoic acid, or *trans,cis*-10,12-octadecadienoic acid can be incorporated into a composition such as food composition. de Boer et al. does not expressly teach that the amount of the conjugated linoleic acid is about 1mg to about 10,000mg/kg of body weight in the invention.

Francisco et al. teaches type II diabetes patient may have elevated insulin and impaired glucose tolerance (See page 1122, col.1 and Table 66.2). Francisco et al. teaches elevated glucose level as one of the classic symptoms of diabetes (See page 1124, col. 1, first and second paragraphs).

Cook et al. teaches a method of adding conjugated linoleic acid (CLA) compounds into animal feed to reduce fat in the animal (see particularly claim 1). Cook et al. also teaches the conjugated linoleic acid compounds to be used may include *trans,cis*-9,11-octadecainoic acid or *cis,cis*-9,11-octadecadienoic acid or *trans,cis*-10,12-octadecadienoic acid (See particularly col. 4, line 48 to col.5 line 8). Cook et al. also teaches the amount of CLA be employed as 0.001g/kg to 1g/kg (See col. 5, line 9-13).

It would have been obvious to one skill in the art when the invention was made to employ CLA in a method of treating diabetic symptoms of elevated insulin, glucose intolerance, and elevated glucose level. It would have been obvious for one of ordinary skill in the art at the time the invention was made to incorporate about 1mg to about 10,000mg/kg of body weight of the *trans*, *cis*-9,11-octadecenoic acid or *cis,cis*-9,11-octadecadienoic acid or *trans,cis*-10,12-octadecadienoic acid into a milk composition product useful in a method of treating diabetic symptoms of elevated insulin, glucose intolerance, and elevated glucose level.

One of ordinary skill in the art would have motivated to employ CLA in a method of treating diabetic symptoms of elevated insulin, glucose intolerance, and elevated glucose level because de Boer et al. clearly teaches unsaturated fatty acids preferably CLA are useful to treat disorders including diabetes (See particularly col. 1, line 35 to 43) and Francisco et al. teaches that elevated insulin and impaired glucose tolerance as well-known symptoms manifested in diabetic patients. Therefore, administered CLA to diabetic patients would have been reasonably expected to be useful to treat elevated insulin and impaired glucose tolerance.

One of ordinary skill in the art would have been motivated to incorporate the CLA compounds herein in the amounts herein into milk food composition products useful in a method of treating diabetes and the herein claimed associated symptoms because CLAs, broadly, are known to be useful in a method and composition for treating diabetes. Therapeutic effects in the treatment of diabetes, and thus, its classic symptoms such as elevated insulin, glucose intolerance, and elevated glucose level

would have been reasonably expected when using any particular known CLA compounds including the compounds herein in a composition or method to treat diabetes.

Optimization of result effect parameters (e.g., amount and concentrations of composition ingredients to be employed) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Response to Arguments

Applicant's arguments filed JUNE 9, 2004 averring de Boer's teachings as ambiguous has been considered but not found persuasive because de Boer et al. teaches that unsaturated fatty acid, especially linoleic acid, whether it is conjugated or not, is useful in the treatment of diabetes (See col. 1, lines 35-42; particularly line 39 and 40). In this passage, de Boer et al clearly teaches that both conjugated or unconjugated linoleic acid is useful in treating diabetes. Taking with the teachings of Francisco and Cook, one of ordinary skill in the art would have been motivated to administer CLA to diabetic patients for the treatment diabetes and its classic symptoms, absent evidence to the contrary.

Applicant's arguments filed JUNE 9, 2004 averring the declaration of Dr. Burley filed JUNE 9, 2004 providing evidence to show that CLA as particularly effective in treating the herein claimed diabetic symptoms have been considered, but are not found persuasive. Examiner notes that the articles provided in attempt to show unobviousness are mostly published after the effective filing date of the instant

application, except for Lerman et al. Unobviousness has to be established at the time the invention was made. Therefore, the teachings of the articles published after the effective filing date of the instant application are not considered probative evidence for obviating the rejection set forth in the instant office action. Moreover, Lerman et al. actually provide more basis of supporting the unsaturated fatty acid as effective to lower glucose level in the NIDDM patients (See page 313, Table 3, see the comparison of glycemia before and after the diet). Furthermore, the declaration by Dr. Burley fails to provide other evidence or data for unexpected benefits other than the articles cited. Therefore, the instant claims are considered properly rejected under 35 USC 103(a).

The paragraph 23 of the declaration of Dr. Burley filed JUNE 9, 2004 have been considered, but are not found persuasive. Examiner notes that data or evidence provided in supporting statements stated in paragraph 23 in the declaration of Dr. Burley (assuming the articles) have been considered, and addressed in the previous paragraph above.

Applicant's arguments filed JUNE 9, 2004 averring Cook's failure to obviate the deficiency of de Boer have been considered, but are not found persuasive in view of the new ground of rejection. Francisco teaches the herein claimed symptoms as classic symptoms of type II diabetes. Thus, possessing the teachings of the cited prior arts, one of ordinary skill in the art would have been motivated to administer CLA to diabetic patients for the treatment diabetes and its classic symptoms.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



San-ming Hui
Patent Examiner
Art Unit 1617